

## Rhythm Biosciences Quarterly Report March 2020

### Quarter Highlights:

- **Biomarker and antibody panel testing progressing for ColoSTAT®;**
- **Adjunct biomarkers undergoing optimisation; and**
- **\$2.85 million of cash on hand at 31 March 2020.**

### Subsequent to period-end:

- **Successful technical validation of key lead biomarker for ColoSTAT®, reducing development risk;**
- **Retention of ISO13485:2016 certification of its Quality Management System, a key step to commercialisation; and**
- **Update provided on COVID-19 effects.**

**23 April 2020**, Melbourne: For the quarter ended 31 March 2020, medical diagnostics company Rhythm Biosciences Limited (ASX: RHY) continued the development of ColoSTAT®, its global, low-cost, lifesaving blood test for the early detection of colorectal cancer.

### Lead Biomarker Technically Validated

Rhythm's internal test development program focused on developing the individual biomarkers found in the ColoSTAT® test, resulting in the key lead biomarker antibodies successfully being technically validated (released 2 April 2020). Further, as a part of this testing, it was confirmed that the antibodies are stable, and the test is reproducible. This key, lead biomarker is the primary biomarker which can differentiate between cancerous and healthy blood samples and is the principal ingredient of the ColoSTAT® test. Technical validation of this lead biomarker significantly mitigates the overall risk in the development of ColoSTAT.

### ISO Certification

Importantly during the period, Rhythm successfully maintained its certification to the International Standard for In-Vitro Diagnostics and Medical Devices (ISO 13485:2016). The audit was conducted by the British Standards Institution (BSI). This certification is an important step in achieving European market entry via a CE Mark and for the Australian market via the Therapeutic Goods Administration (TGA).

### COVID-19 Update

As per the COVID-19 Update (released 9 April 2020) Rhythm is pleased to have been able to, for the most part, maintain essential laboratory R&D staff working upon the individual biomarker technical validation, however, the Company is experiencing some delays in the receipt of various materials from international sources (including Europe and the USA). Delays have also been experienced within patient recruitment and blood sample collection for both Study 6 and the clinical trial (Study 7). This has been exacerbated by delays in the approval of additional trial sites. The Company expects recruitment to recommence, and additional trial sites to be added when the hospital operating landscape normalises.

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**Rhythm Biosciences**ACN: 619 459 335  
ASX: RHY**Issued Capital**100,750,000 Shares  
3,000,000 Options**Australian Registered Office**Level 17, 500 Collins Street  
Melbourne VIC 3000  
[www.rhythmbio.com](http://www.rhythmbio.com)**Directors**Otto Buttula – Chairman of the Board  
Trevor John Lockett – Executive Director  
Louis James Panaccio – Non-Executive Director  
David John White – Non-Executive Director

Rhythm notes the Federal Government's announcement (21 April 2020) regarding the resumption of Category 2 and some Category 3 elective surgeries. This is hugely encouraging, with Rhythm actively working with its Clinical Research Organisation (CRO) and the clinical trial sites themselves to assess the impact on specific hospitals. Particularly crucial to Rhythm's trial outcomes, is that there are appropriate numbers of clinical trial staff resuming their roles (in some capacity) to allow recruitment and appropriate collections to re-commence.

Rhythm will keep stakeholders informed of progress in a COVID-19 update scheduled for release at the end of next month, or earlier if material.

## **Operations / Corporate**

Rhythm's development focus continues to be upon the optimisation and technical validation of its proprietary version of antibodies which will be combined in the ColoSTAT® test.

Despite some COVID-19 induced delays, the global unmet need and market opportunity for Rhythm's ColoSTAT® test kit has not diminished. ColoSTAT®, being a simple blood test, has the potential to be a diagnostic tool that should increase global compliance of participating countries within their national bowel cancer screening programs. The positive health economic benefits from early detection of colorectal cancer from the introduction of ColoSTAT® should enhance its potential to attract reimbursement by both governments and health insurance companies.

The regulatory process remains as planned, with the completion of analytical testing and the final clinical trial report forming supporting evidence for ColoSTAT®'s suitability for use in detecting colorectal cancer, which will then underpin applications for a CE mark in the European Union (EU) and Therapeutic Goods Administration (TGA) approval in Australia.

Rhythm finished the March 2020 quarter with a cash balance of \$2.85 million.

With authority by the Board.

For further information, please contact:

Glenn Gilbert  
Chief Executive Officer  
+61 3 8256 2880

## **About Rhythm Biosciences**

ASX-listed Rhythm Biosciences is endeavoring to develop and commercialise a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

ColoSTAT® is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure.

ColoSTAT® has the potential to play an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer. Globally, over 850,000 people die from colorectal cancer each year.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

RHYTHM BIOSCIENCES LIMITED

**ABN**

59 619 459 335

**Quarter ended ("current quarter")**

31 MARCH 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(521)	(1,713)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (not included above)	(107)	(387)
(f) administration and corporate costs	(135)	(441)
1.3 Dividends received (see note 3)		
1.4 Interest received	12	38
1.5 Interest and other costs of finance paid	(2)	(6)
1.6 Income taxes paid		
1.7 Government grants and tax incentives		744
1.8 Other (provide details if material)	13	13
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(740)</b>	<b>(1,752)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(17)	(21)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(17)</b>	<b>(21)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings	(40)	(105)
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(40)</b>	<b>(105)</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	3,647	4,728
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(740)	(1,752)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(17)	(21)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(40)	(105)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	<b>Cash and cash equivalents at end of period</b>	<b>2,850</b>	<b>2,850</b>

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	835	632
5.2	Call deposits	2,015	3,015
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,850</b>	<b>3,647</b>

**6. Payments to related parties of the entity and their associates**

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

82

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Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

*Payments relate to director fees and consulting services.*

**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	33	33
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 <b>Total financing facilities</b>	33	33

**7.5 Unused financing facilities available at quarter end**

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7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Bank of Queensland Insurance loan. Unsecured. Interest rate: 4.99% p.a. Matures on 17/07/2020 with fixed repayments.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(740)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	2,850
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	2,850
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	3.85

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

- Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: n/a

- Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: n/a

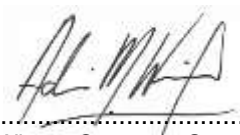
- Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: n/a

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: .....23 April 2020.....

Authorised by: .....  
(Adrien Wing – Company Secretary)  
(With authority by the Board)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.